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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,723	SHORT ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,23-31,38-45,48,49,58-65,81-86,100-110,116-121,132,133 and 170-172* is/are rejected.

7)☒ Claim(s) *13,14 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7032003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-10,13,14,23-31,33,38-46,48,49,58-65,81-86,100-110,116-121,132,133 and 170-172.

DETAILED ACTION

Election/Restrictions

1. Applicants' election of Group I, claims 1-46, 48, 50, 52, 54, 56, 58, 60-65, 81-86, 100-110, 116-121, 132, 133, 170-172 in the reply filed on February 19, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants' election with traverse of SEQ ID NO: 3 and 13 in the same reply is acknowledged. The traversal is on the ground(s) that SEQ ID NOs: 3 and 11 are synthetically generated sequences based on a *Yersinia pestis* phytase. However, Applicants have already deleted SEQ ID NO: 11 from the claims, rendering the issue moot.

The requirement is still deemed proper and is therefore made FINAL. Note that because claim 46 is directed to a non-elected invention (SEQ ID NO: 2), it is withdrawn from consideration. Claims 1-10, 13-14, 23-31, 33, 38-45, 48, 49, 58-65, 81-86, 100-110, 116-121, 132133, and 170-172 have been examined in this Office action.

Specification

2. Page 70, line 20, of the specification recites U.S. Serial No. 08/692,002. This citation should be amended to indicate the status of the application (abandoned or, if issued, the patent number).

3. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable codes, for example on page 91, lines 6, 14-17, 23; page 93, line 16. Applicant is required to delete these and all other embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

4. Page 122, line 32 mentions a co-pending U.S. patent application. However, a blank line appears instead of the serial number. Correction/clarification is required. If the blank line is replaced with a serial number, the status of the application (abandoned or, if issued, the U.S. Patent No.), should be inserted.

5. Page 145, line 4, recites "U.S. Patent No. XXXXXX." The actual patent number must be inserted.

6. Page 147, lines 10 and 18 recite "Figure X". There is no such figure labeled "X." Correction/clarification is required. New matter must be avoided.

7. Page 148, line 10, recites, "results presented in Figure". The figure number needs to be inserted.

8. The specification fails to comply with the sequence rules of 37 CFR 1.821-1.825. Figure 6A-6C display 6 amino acid sequences. However, the brief description of Figure 6 on page 18 only provides 5 sequence identifiers. The sequence identifier for the sixth sequence must be

inserted into either Figure 6 or the brief description. Further, it is not clear which sequence identifier belongs to which sequence in the figures.

9. Figure 6 contains multiple views that are labeled with a letter (A-C). However, the brief description of the figure in the specification on page 18 does not recite the labels. The description should be amended to recite the labels. See 37 CFR 1.74.

10. Brief descriptions of Figures 8-11, 12A-12B, 13A-13B, and 14 are not provided in the specification. Brief descriptions of those figures should be inserted. Further regarding Figure 9- the brief description for this figure should include a sequence identifier that identifies the amino acid sequence in this figure. New matter must be avoided.

11. Page 17, line 3 recites amino acid sequences that require to be identified by their sequence identifiers. See 37 CFR 1.821-1.825.

Drawings

12. Applicants submitted formal drawings on September 9, 2002. Page 1 of the transmittal letter that accompanied the drawings indicates that 27 pages of drawings were submitted, for figures 1-14. However, only 21 pages of drawings were received. Formal drawings for Figures 5J-5N, for which brief descriptions appear on page 18 of the specification, were not received. It is also noted the brief descriptions for these figures indicate that they present amino acid and nucleotide sequences. The figures should recite the sequence identifiers corresponding to these

sequences, or the brief descriptions should be amended to recite them, in accordance with 37 CFR 1.821-1.825.

Claim Objections

13. Claims 2-10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Parent claim 1 is directed to any isolated or recombinant nucleic acid comprising a nucleotide sequence selected from SEQ ID NO: 3, SEQ ID NO: 13, and complements thereof. Claims 2-7 encompass isolated or recombinant nucleic acids that are at least 50%-95% identical to a sequence of the nucleic acid of claim 1. Claims 8-10 encompass nucleic acids that hybridize to those of claim 1. However, claim 1 does not encompass these nucleic acids. Claims 2-10 therefore do not limit the subject matter of claim 1. Isolated or recombinant nucleic acids that are less than 100% identical to the specific nucleic acids of claim 1, would not infringe claim 1.

14. Claims 81-86 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 100-105. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 81 and 100 are exactly identical. Claims 82, 8, and 86, all

dependent on claim 81, introduce the same limitations as claims 101, 104, and 105, all dependent on claim 100. Claims 82 and 102 also encompass the same subject matter.

15. Claims 13, 14, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-10 and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 23, and 24: the claims are indefinite because they indicate that SEQ ID NO: 13 is a nucleotide sequence, whereas the sequence listing indicates that SEQ ID NO: 13 sets forth an amino acid sequence. Therefore claims 1, 23, and 24, and those dependent thereon, cannot be further examined for SEQ ID NO: 13, as the meaning of the claims regarding this sequence is not clear.

In claims 8-10: the recitation, "high stringency", "moderate stringency", or "low stringency" renders the claims indefinite. The specification, in the paragraph bridging pages 25-26, lists some conditions under which "could" be highly stringent. However, it is not clear what is meant by "could." The recitation indicates that these conditions may not necessarily be

considered highly stringent. Further, this discussion does not list other conditions that are considered to be high stringency. The specification also does not provide closed definitions for "moderate" and "low" stringency, that include all examples of what such conditions are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 2-10, 25-30, 45, 48, 58, 60-65, 81-86, 100-110, 116-121, 132, and 133 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated or recombinant nucleic acid at least 50% to at least 95% identical to the nucleotide sequence of SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3, or the complement of SEQ ID NO: 13; or any isolated or recombinant nucleic acid that hybridizes to SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3, or the complement of SEQ ID NO: 13 under high, moderate, or low stringency conditions; an expression vector or any host cell, of any species, comprising isolated or recombinant nucleic acids at least 95% identical to the nucleotide sequence of SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3, or the complement of SEQ ID NO: 13; or any isolated or recombinant nucleic acid that hybridizes to SEQ ID NO: 3, SEQ ID NO: 13, the

complement of SEQ ID NO: 3; or any isolated or recombinant nucleic acid comprising a nucleotide sequence encoding any polypeptide having at least thirty contiguous amino acids of a polypeptide having an amino acid sequence from SEQ ID NO: 4 or SEQ ID NO 14, any expression vector or host cell, of any species, comprising said nucleic acid; any nucleic acid expression vector comprising any nucleotide sequence encoding a polypeptide having at least 95% sequence identity to SEQ ID NO: 4 or SEQ ID NO: 14, or encoding a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14, any expression vector or host cell, of any species, comprising said nucleic acid vector; a method to produce an animal feed comprising transforming a plant, plant part, or plant cell with a nucleic acid vector comprising any nucleotide sequence encoding a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14; any non-human transgenic organism comprising a heterologous nucleic acid encoding a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14; a feed composition comprising a plant, plant part, or plant cell expressing a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14, and a phytate-containing foodstuff.

The specification indicates a gene encoding a phytase was isolated from *Yersinia pestis*. The amino acid sequence encoded by the originally isolated sequence was incomplete for several amino acids, that occurred at positions 157, 163, 164, and 174 of SEQ ID NO: 2. The sequences were changed in a synthetic gene, SEQ ID NO: 3, that was produced by inserting the nucleotide sequences encoding the corresponding amino acids these positions in the *Escherichia coli* appa phytase (page 144, lines 26-31). The brief description of Figure 6 indicates that SEQ ID NOs: 4

and 14 are phytases (page 18, lines 19-20). Figures 5C and 5D present the nucleotide and encoded amino acid sequence of the corrected *Y. pestis* phytase.

A review of the language of claim 2 indicates that it is drawn to a broad genus, any isolated or recombinant nucleic acid at least 95% identical to a sequence of SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3, or the complement of SEQ ID NO: 13. As discussed above in the indefiniteness rejection, SEQ ID NO: 13 is an amino acid sequence, not a nucleotide sequence. Claim 2 does not recite any functional language. The nucleic acids of the claim therefore can have any function. Claims 3-7 are similarly directed to isolated or recombinant nucleic acids, wherein the nucleic acid is at least 90%, 80%, 70%, 60%, or 50% identical to the nucleotide sequence of SEQ ID NO: 3 and its complement.

However, the specification does not describe any of the claimed nucleic acids, other than those of SEQ ID NO: 3 and its complement, and non-elected sequences in the sequence listing. The specification does not describe the sequences of SEQ ID NO: 3 that are essential to its function, such as those that encode catalytic and binding sites in SEQ ID NO: 4. The specification does not correlate other structures to the function of having phytase activity. The specification also does not describe any functions for SEQ ID NO: 3 or other claimed nucleic acids. The specification also does not mention anything about the functions of the nucleic acids that have sequence identity to the complement of SEQ ID NO: 3, which are also encompassed by claims. Such sequences do not encode phytase. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which teaches "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter

sufficient to distinguish it from other materials." The court also held in *Lilly* that a genus of cDNAs could be described by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

A review of the language of claims 8-10 indicates that the claims are drawn towards isolated or recombinant nucleic acids that hybridize to SEQ ID NO: 3 or its complement under high, moderate, or low stringency conditions. However, it is well known in the art that moderate and low stringency hybridization conditions allow the binding of non-specific nucleotide sequences to a template sequence. The specification provides no information at all about nucleotide sequences that do not encode phytases. Further, claims 8-10 encompass nucleotide sequences that hybridize to SEQ ID NO: 3. The sequences that bind to SEQ ID NO: 3 would not be expected to encode phytases. The function of such sequences are not mentioned in the specification. Furthermore, the claims do not recite any functional language, and therefore encompass nucleotide sequences having any function, including those that are not described in the specification.

A review of the language of claims 45, 48, and 49 indicates that they are drawn to a broad genus, any isolated or recombinant nucleic acid comprising any nucleotide sequence

encoding any polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14. Claims 60-65 are directed to expression vectors and host cells that comprise the nucleic acid. Claims 106-110 are also drawn to nucleic acid expression vectors comprising the same nucleotide sequences. Claims 116-118 are directed to a method to produce an animal feed comprising transforming a plant, plant part or plant cell with the nucleic acid vector of claim 106. Claims 119-121 are rather broadly drawn towards any and all non-human transgenic organisms, or plants, comprising said nucleotide sequences. Claims 132 and 133 are directed to feed composition comprising a plant, plant part or plant cell expressing said polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14, and phytate-containing foodstuff.

As discussed above, the specification indicates that SEQ ID NOs: 4 and 14 are phytases. However, the specification does not describe the function of nucleic acid sequences encoding proteins that differ from SEQ ID NOs: 4 and 14, including those that have as few as 30 contiguous amino acids of the 420 and 318 amino acids of SEQ ID NOs: 4 and 14, respectively. The specification does not indicate that as few as 30 contiguous amino acids of SEQ ID NOs: 4 and 14 will retain phytase activity, nor does it correlate phytase activity with any amino acid sequence that comprises any 30 contiguous amino acids of SEQ ID NOs: 4 and 14. Further, the claims do not recite any functional language, and therefore encompass nucleic acids that encode polypeptide having any activity. The specification also does not mention any other function for the claimed nucleotide sequences. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., *supra*.

A review of claims 81-86 and 100-105 indicate that they are drawn to a genus, nucleic acid expression vectors comprising a nucleotide sequence encoding any polypeptide having at

least 95% sequence identity to SEQ ID NO: 4 or SEQ ID NO: 14; or host cells transformed with the vector. The polypeptides encoded by the nucleotide sequences may have any activity, as the claims do not recite any functional language.

However, the specification does not describe any function for SEQ ID NOs: 4 and 14 other than having phytase activity. No other function is correlated by the specification with these sequences. It is suggested that claim 102 be amended to indicate that the polypeptides have the phytase activity of SEQ ID NOs: 4 and 14. Given the breadth of the claims encompassing nucleotide sequences encoding amino acid sequences differing from SEQ ID NOs: 4 and 14 and nucleotide sequences encoding polypeptides having any function, it is submitted that the specification fails to provide an adequate written description of the multitude of nucleic acid sequences encompassed by the claims.

18. Claims 2-10, 25-31, 38-45, 48, 49, 58-65, 81-86, 100-110, 116-121, 132, 133, 170-172 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated or recombinant nucleic acid comprising SEQ ID NO: 3, or nucleotide sequences encoding SEQ ID NO: 4, does not reasonably provide enablement for other nucleotide sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any isolated or recombinant nucleic acid at least 50% to at least 95% identical to the nucleotide sequence of SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3, or the complement of SEQ ID NO: 13; or any isolated or

recombinant nucleic acid that hybridizes to SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3, or the complement of SEQ ID NO: 13 under high, moderate, or low stringency conditions; an expression vector or any host cell, of any species, comprising isolated or recombinant nucleic acids at least 95% identical to the nucleotide sequence of SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3, or the complement of SEQ ID NO: 13; or any isolated or recombinant nucleic acid that hybridizes to SEQ ID NO: 3, SEQ ID NO: 13, the complement of SEQ ID NO: 3; or any isolated or recombinant nucleic acid comprising a nucleotide sequence encoding any polypeptide having at least thirty contiguous amino acids of a polypeptide having an amino acid sequence from SEQ ID NO: 4 or SEQ ID NO 14, any expression vector or host cell, of any species, comprising said nucleic acid; any nucleic acid expression vector comprising any nucleotide sequence encoding a polypeptide having at least 95% sequence identity to SEQ ID NO: 4 or SEQ ID NO: 14, or encoding a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14, any expression vector or host cell, of any species, comprising said nucleic acid vector; a method to produce an animal feed comprising transforming a plant, plant part, or plant cell with a nucleic acid vector comprising any nucleotide sequence encoding a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14; any non-human transgenic organism comprising a heterologous nucleic acid encoding a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14; a feed composition comprising a plant, plant part, or plant cell expressing a polypeptide having at least 30 contiguous amino acids of SEQ ID NO: 4 or SEQ ID NO: 14, and a phytate-containing foodstuff; or any isolated nucleic acid encoding a

phytase having an amino acid sequence selected from the group consisting of SEQ ID NOs: 4 or 14 and optimized for codon usage in any organism.

The specification indicates a gene encoding a phytase was isolated from *Yersinia pestis*. The amino acid sequence encoded by the originally isolated sequence was incomplete for several amino acids, that occurred at positions 157, 163, 164, and 174 of SEQ ID NO: 2. The sequences were changed in a synthetic gene, SEQ ID NO: 3, that was produced by inserting the nucleotide sequences encoding the corresponding amino acids in these positions in the *Escherichia coli* appa phytase (page 144, lines 26-31). The brief description of Figure 6 indicates that SEQ ID NOs: 4 and 14 are phytases (page 18, lines 19-20). Figures 5C and 5D present the nucleotide and encoded amino acid sequences of the corrected *Y. pestis* phytase (SEQ ID NOs: 3 and 4).

The specification does not teach nucleotide sequences that encode polypeptides that differ from SEQ ID NO: 4 and which encode phytases. The specification does not provide any guidance in how one skilled in the art would change the sequence of SEQ ID NO: 3 or 4 without altering its phytase activity. No guidance is provided regarding the amino acids of SEQ ID NO: 4 that can be changed without altering functional activity. The specification also does not teach nucleotide sequences encoding a polypeptide having at least 30 contiguous amino acids of SEQ ID NOs: 4 or 14. The specification does not teach that any 30 contiguous amino acids of SEQ ID NOs: 4 and 14 retain their phytase activities. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine how the sequences of SEQ ID NOs: 3 and 4 may be changed without altering phytase activity, or to prepare nucleotide sequences that encode as few as any 30 contiguous amino acid sequences of SEQ ID NOs: 4 and 14 that retain their phytase activities. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d

1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Further, the claims encompass nucleic acids that encode polypeptides that can have any function. However, the specification does not mention other functions for the claimed sequences.

It is also well accepted that non-specific nucleotide sequences hybridize to a template nucleotide sequence under moderate and low stringencies. Such sequences are encompassed by the claims. However, the specification does not teach how one skilled in the art is to use such sequences. See Genentech, Inc. v. Novo Nordisk, A/S, *supra.*

Further, the specification does not teach any nucleotide sequence encoding SEQ ID NO: 14. While the specification indicates that SEQ ID NO: 14 has phytase activity, as discussed above, no information is provide about the nucleotide sequence that encodes it. An amino acid sequence does not teach the nucleotide sequence that encodes it. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein.

The claims also encompass transformed host cells, of any species, and any and all non-human transgenic organisms. However, the specification does not teach transformation methods for all cells of all species and all non-human organisms. The prior art also does not indicate that transformation methods for all cell types of all species and all non-human organisms were known at the time the instant application was filed. The specification only provides general statements that host cells can be grow in conventional nutrient media and appropriate culture conditions (page 37, lines 16-22). However, conventional media and appropriate culture conditions are not

provided for all cell types. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine how to transform all cell types and all non-human transgenic organisms. Further, while the benefit of adding phytase to phytate-containing foodstuffs is discussed, the specification is silent as to the effect of expression of the claimed nucleic acids on all hosts encompassed by the claims. See Genentech, Inc. v. Novo Nordisk, A/S, *supra*.

Claims 170 and 171 encompass optimizing nucleic acids encoding SEQ ID NOs: 4 and 14 for codon usage in any and all organisms, or in any and all plants, bacteria, fungi, and animals. However, while codon usage for many organisms were known at the time of the invention, the specification and prior art do not teach the optimal codon usage for all known organisms. Undue experimentation would be required by one skilled in the art to determine the preferred codons used by any and all organisms. It is suggested that the claims be cancelled, as claim 31 encompasses all nucleotide sequences that encode SEQ ID NOs: 4 and 14. Given the breadth of the claims, unpredictability of the art, and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

19. Claims 1-10, 23-31, 38-45, 48, 49, 58-65, 81-86, 100-110, 116-121, 132, 133, and 170-172 are rejected. Claims 13, 14, and 33 are objected, and claim 46 is withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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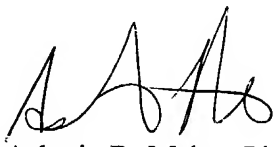

June 24, 2004

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638